

# Exhibit 10

1 UNITED STATES DISTRICT COURT  
 2 FOR THE NORTHERN DISTRICT OF OHIO  
 3 EASTERN DIVISION

4 IN RE: NATIONAL ) MDL No. 2804  
 PRESCRIPTION OPIATE )  
 5 LITIGATION ) Case No.  
 ) 1:17-MD-2804  
 )  
 6 THIS DOCUMENT RELATES TO ) Hon. Dan A.  
 ALL CASES ) Polster  
 )

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 9  
 10 Tuesday, May 14, 2019  
 11

12 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER  
 CONFIDENTIALITY REVIEW  
 13  
 14  
 15

16 Videotaped Deposition of JAMES E.  
 RAFALSKI, VOLUME 2, held at Weitz &  
 17 Luxenburg PC, 3011 West Grand Avenue, Suite  
 2150, Detroit, Michigan, commencing at  
 18 8:25 a.m., on the above date, before  
 Michael E. Miller, Fellow of the Academy of  
 19 Professional Reporters, Registered Diplomate  
 Reporter, Certified Realtime Reporter and  
 20 Notary Public.  
 21  
 22  
 23

24 GOLKOW LITIGATION SERVICES  
 877.370.3377 ph | fax 917.591.5672  
 25 deps@golkow.com

<p style="text-align: right;">Page 632</p> <p>1 that. It's just that I wasn't tasked to 2 provide that methodology in regards to 3 manufacturers at this time. 4 Q. I understand. But your report 5 doesn't identify any suspicious orders that 6 were submitted by distributors to 7 manufacturers. 8 A. My report would only identify 9 those orders that the manufacturers have 10 identified. I don't make any independent 11 calculations or apply any algorithms to 12 identify it outside of what's in my report 13 stated as I've discovered as part of this 14 discovery. 15 Q. Okay. So other than the 16 reports that the manufacturers themselves 17 reported to DEA, you have not identified any 18 suspicious orders submitted by distributors 19 to manufacturers, correct? 20 A. Can I ask a clarification? Are 21 you talking about an individual order or are 22 you talking about conduct? 23 Q. I'm talking about individual 24 orders. 25 A. I have not done that as we sit</p>	<p style="text-align: right;">Page 634</p> <p>1 (Document review.) 2 A. I don't believe so, no, sir. 3 BY MR. O'CONNOR: 4 Q. Okay. And at trial, do you 5 intend to offer any opinion regarding whether 6 any particular order submitted to a 7 manufacturer was suspicious? 8 A. If I'm requested to do that 9 analysis by counsel, I guess that would be a 10 possibility. I haven't done the analysis as 11 today, so I couldn't offer that opinion. 12 Q. So as you sit here today, you 13 do not have an opinion on whether any 14 particular order that was shipped by a 15 manufacturer was suspicious? 16 A. I think I have an opinion. 17 Q. But you haven't identified any 18 order, correct? 19 A. I have not identified a 20 specific order, but I have an opinion on the 21 conduct. 22 Q. And are you offering any 23 opinion in this litigation that any 24 particular order that was shipped into Summit 25 or Cuyahoga Counties was suspicious?</p>
<p style="text-align: right;">Page 633</p> <p>1 here today, no, sir. 2 Q. Okay. So your report does not 3 identify any shipments by manufacturers to 4 distributors that you claim should have been 5 reported as suspicious? 6 A. My opinion goes to whether or 7 not there were effective -- or suspicious 8 orders, effective suspicious order systems in 9 place and/or the maintenance of effective 10 controls, the due diligence. I do not do any 11 calculations that would identify any specific 12 orders. 13 Q. Okay. So just to be clear, in 14 response to my question, your report does not 15 identify any shipments by manufacturers to 16 distributors that you claim should have been 17 reported as suspicious, correct? 18 A. I think there's some instances 19 in my report, there was -- there may be a 20 description of a relationship or some 21 transactions between a -- let me think a 22 second. 23 Q. Uh-huh. 24 A. Because I have all of the 25 different companies.</p>	<p style="text-align: right;">Page 635</p> <p>1 A. Yes. 2 Q. Okay. And are you offering any 3 opinion in this litigation that any 4 particular order shipped by a manufacturer 5 into Summit or Cuyahoga County was 6 suspicious? 7 A. I'm sorry, shipped by a 8 manufacturer -- 9 Q. Correct. 10 A. -- to a distributor? 11 Q. That's right. To -- to someone 12 in Cuyahoga or Summit County. 13 A. No, sir. 14 Q. Okay. With respect to a 15 manufacturer, what is a suspicious order? 16 A. Well, if a manufacturer has 17 conducted a sufficient due diligence or 18 onboarding process and they've evaluated the 19 scope of their customers' business and the 20 needs, they would establish a pattern, and 21 that pattern would give them an idea of 22 initially the volume of drugs they need to 23 purchase. 24 Now, if it's brand-new 25 customer -- yours is kind of a hypothetical.</p>

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1 If it's a brand-new customer, there's not a  
 2 pattern or a frequency, but they would start  
 3 out with what they assess as a legitimate  
 4 volume, and they would monitor that volume,  
 5 and if a customer exceeded that, that should  
 6 trigger as an unusual size.

7 But to give you just a general  
 8 definition, it's kind of a broad topic  
 9 because it depends on the scope of business  
 10 of the manufacturer, of the customer, the  
 11 type of products, the needs, so the -- prior  
 12 to ever shipping an order, the importance is  
 13 to understand what the legitimate needs is of  
 14 a customer.

15 Q. Yesterday you testified that it  
 16 was important to understand what a usual  
 17 order was so that you could determine what a  
 18 suspicious order was.

19 Do you generally recall that  
 20 testimony?

21 A. I think that's a general  
 22 description. I think we were discussing the  
 23 size, so I think before you would know an  
 24 unusual size, you would need to know the  
 25 usual size.

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1 And I think that's kind of the  
 2 simpler way of what I just said, is that if  
 3 you don't really have a comprehension of what  
 4 is the legitimate needs of your customer,  
 5 then you couldn't know an unusual order --  
 6 unusual size of an order, I'm sorry.

7 Q. What information would you need  
 8 to determine what a usual order looked like  
 9 for a manufacturer?

10 MR. FULLER: Form.

11 THE WITNESS: I'm sorry, you  
 12 said something?

13 MR. FULLER: Object to form.

14 THE WITNESS: Oh. Sorry.

15 A. I think that's dependent on the  
 16 skill of your compliance employees. I think  
 17 you go in and evaluate the distributor. I  
 18 don't think the distributor would purchase a  
 19 manufacturer's product with an idea on how  
 20 they were going to sell it and market it, and  
 21 I think you would evaluate what their scope  
 22 of business is and the type of customers they  
 23 were; how many pharmacies they could  
 24 distribute to.

25 I think you'd have to get some

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1 baseline information to get a gauge on how  
 2 much product you'd want to send to them. I  
 3 don't think you would just send them an  
 4 amount of product and hope they distribute  
 5 it. I think there should be some kind of a  
 6 relationship and identification of a  
 7 legitimate total.

8 BY MR. O'CONNOR:

9 Q. Besides understanding what type  
 10 of pharmacy -- or what type of customer or  
 11 the number of customers a distributor had,  
 12 what other information would you say a  
 13 manufacturer needs to know in order to  
 14 establish a baseline?

15 A. A baseline in regards to size?

16 Q. Correct.

17 A. Well, I think there would be  
 18 some other factors that they should minimally  
 19 look at. That would be the ability for the  
 20 company to actually handle the volume of  
 21 product on a security aspect, they had  
 22 sufficient cage or vault depending on the  
 23 schedule of controlled substance they were  
 24 purchasing.

25 I think they may want to do

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1 some analysis of the identifications of the  
 2 pharmacies, if possible, because it's a  
 3 potential that in the case of Mallinckrodt,  
 4 they might already have information about the  
 5 distribution amounts or the purchase amounts  
 6 for those pharmacies and some trends.

7 Might do some comparison to  
 8 like customers. Might look into the  
 9 geographic location of where the product is  
 10 intended to be distributed. At least for the  
 11 Mallinckrodt products, to confirm or deny  
 12 there might be an issue of a distribution by  
 13 volume to those specific areas.

14 I think the essential thing is  
 15 what I said initially. I think you need to  
 16 get an idea of how many customers that that  
 17 distributor intends to distribute.

18 And I think if we're talking  
 19 about the onboarding or the initial amounts  
 20 that they'll be distributing, I think that a  
 21 registrant should follow those pretty closely  
 22 because my experience would indicate that  
 23 sometimes other registrants aren't that  
 24 truthful, and not just because they want to  
 25 divert, although that's one of the

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1 recollection is they did not implement their  
2 system.

3 Q. What do you mean they didn't  
4 implement their system?

5 A. Buzzeo was not retained as a  
6 consultant and the Buzzeo system was not  
7 implemented at the company.

8 Q. And at that time, he was  
9 reviewing the Suspicious Orders I system for  
10 Teva, correct?

11 A. I think that's an accurate  
12 statement, yes.

13 Q. And at no point does the report  
14 conclude that Teva's suspicious order  
15 monitoring system was not compliant with DEA  
16 regulations; isn't that a correct statement?

17 A. Say that again.

18 Q. At no point in Mr. Buzzeo's  
19 report does he conclude that the Teva  
20 suspicious order monitoring system was not  
21 compliant with DEA regulations; wouldn't you  
22 agree?

23 A. I think -- I think he was  
24 critical of the functionality of it, but in  
25 reading other reports by Mr. Buzzeo, I don't

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1 think he draws -- makes that conclusion. At  
2 least he doesn't put it in his reports,  
3 because he's not a DEA representative.

4 Q. The DEA regulations don't state  
5 what type of suspicious order monitoring  
6 model a registrant has to use; isn't that  
7 correct?

8 A. No, it's up to the registrant  
9 to design their system that meets their  
10 business needs and accomplishes the  
11 identification of suspicious orders.

12 Q. And it doesn't state anything  
13 about what standard deviations or what number  
14 of standard deviations a registrant should  
15 use in its algorithm for monitoring  
16 suspicious orders?

17 A. It does not give guidance in  
18 that area.

19 Q. At the time the Buzzeo  
20 report -- I'm sorry, strike that.

21 The Buzzeo report concluded  
22 that SORDS II, which is an improvement on the  
23 SORDS I suspicious order monitoring program,  
24 that Teva had in place was an improvement  
25 over SORDS I; isn't that correct?

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1 A. I believe he did make that  
2 comment, yes. He didn't say that it was  
3 sufficient to be compliant, but he did say it  
4 was an improvement.

5 Q. But again, he didn't say that  
6 it wasn't compliant with DEA regulations?

7 A. No, I didn't say that.

8 Q. My question to you is: He  
9 didn't say that it wasn't compliant with DEA  
10 regulations?

11 A. He never made that exact  
12 statement.

13 Q. Teva also had an internal audit  
14 of its own suspicious order monitoring  
15 program?

16 A. I believe so, yes.

17 Q. And that program was rated  
18 overall as effective, correct?

19 A. Yes, but it's an internal  
20 audit.

21 Q. The DEA regulations don't  
22 require that companies actively audit their  
23 own programs, correct?

24 A. No, that's true. But I only  
25 make that statement because sometimes the

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1 person that does the audit, without knowing  
2 the full information on the audit, is the  
3 person in charge of the system, so they don't  
4 typically give a bad audit to themselves.

5 So, I mean, I'm not totally  
6 discounting it, but I'm always concerned  
7 about internal audits.

8 Q. Mr. Rafalski, in your report  
9 you don't identify any suspicious order that  
10 Teva shipped to Summit County or Cuyahoga;  
11 isn't that correct?

12 A. I do not identify any single  
13 suspicious order -- any order specifically  
14 that was suspicious.

15 Q. And that goes for Cephalon and  
16 the Actavis entities as well, correct?

17 A. As I sit here today, that's an  
18 accurate statement.

19 Q. And you don't identify any  
20 order that Teva failed to flag as suspicious?

21 A. Is that question a specific  
22 order?

23 Q. Any order that Teva failed to  
24 flag as suspicious, you don't have an example  
25 of any specific order?

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1 A. No, I think my examples in here  
2 are more -- go more to the conduct of the due  
3 diligence and it doesn't specifically say  
4 that there was a specific order, but I think  
5 the totality of the incident that I describe  
6 on page 183 I think would include that, but  
7 to answer your question, there's no specific  
8 order where I state that.

9 Q. And I want to ask you quickly  
10 about that order.

11 You're speaking of the Publix  
12 Supermarket pharmacies incident or scenario  
13 that we discussed -- that's in your report on  
14 page 183?

15 A. Yes, I am.

16 Q. The orders involving the Publix  
17 Supermarket pharmacies were not orders placed  
18 from Publix to Teva, were they?

19 A. No, they were placed to a  
20 distributor, an in-between so --

21 Q. Right. They were orders placed  
22 from Publix to Anda, correct?

23 A. Yes. But so the first concern  
24 that I would have with this is that Teva  
25 would need a means of effective controls to

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1 go to Anda and see why this situation  
2 occurred.

3 Q. And it did do that, correct?

4 A. I don't recall that occurring.

5 Q. Well, so you read the  
6 deposition of Joe Tomkiewicz, didn't you?

7 A. Yes.

8 Q. And sitting here today, you  
9 don't know whether any of Teva's product was  
10 ultimately shipped to one of those Publix  
11 Supermarkets that Joe Tomkiewicz identified  
12 as entities he wanted to look into, correct?

13 A. Based on my review, he was  
14 looking at the chargebacks, and I believe  
15 they were Teva products.

16 Q. But you would agree with me  
17 that Joe Tomkiewicz testified he didn't see  
18 any specific orders of Teva's products,  
19 correct?

20 A. Yes, but if they weren't Teva's  
21 products, I'm not sure that he would have  
22 taken all this action unless he was  
23 indicating it was someone else's product that  
24 he was going to go investigate.

25 Q. Well, he could have been

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1 looking at those because Anda is his  
2 customer, correct?

3 A. Yes.

4 Q. Right. And he was looking at  
5 Publix's forecasting data, correct?

6 A. Yes.

7 MR. FULLER: Counsel, I believe  
8 the 14 hours is up.

9 MS. BARBER: All right. At  
10 this time I am going to reserve my  
11 time. I haven't had -- along with my  
12 colleagues, haven't had adequate time  
13 to ask questions of Mr. Rafalski,  
14 which is a violation of our clients'  
15 due process, and we reserve any  
16 additional time in the future to  
17 examine Mr. Rafalski or reexamine  
18 Mr. Rafalski.

19 MS. SWIFT: Before we break,  
20 I'd like to put one additional thing  
21 on the record.

22 Mr. Rafalski, you said your  
23 method for assessing the defendants'  
24 suspicious order monitoring system is  
25 based on your experience, training and

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1 legal guidance from lawyers at the  
2 DEA.

3 Just yes or no, does your Touhy  
4 authorization --

5 MR. FULLER: Don't answer this  
6 question.

7 MS. SWIFT: -- prevent you from  
8 disclosing the legal guidance from DEA  
9 lawyers that supports your opinion?

10 MR. FULLER: Don't answer the  
11 question. She's over her time.

12 Off the record.

13 THE VIDEOGRAPHER: Going off  
14 the record, 4:52 p.m.

15 (Recess taken, 4:52 p.m. to  
16 4:52 p.m.)

17 (The following proceedings were  
18 conducted off the videotaped record.)

19 MR. MATTHEWS: Good afternoon.  
20 This is James Matthews. I represent  
21 Anda Inc. I've sat here for two days  
22 at this deposition and have not asked  
23 any questions because the name Anda  
24 doesn't appear in your report.

25 However, in the last series of